

### REMARKS

This is a response to the Office Action mailed October 8, 2009. No claims are amended herein. Reconsideration of the rejection of claims 1-51 under 35 USC §102(e) as being anticipated by Ray et al. (U.S. Pat. Appln. Pub. No. 2002/0183848) is respectfully requested in view of the inventors' Declarations under 37 C.F.R. §1.131 submitted herewith. A petition for a three (3) month extension of time accompanies this Response. Reconsideration of the rejection is respectfully requested.

The Ray et al. application was filed on July 24, 2002 and was published on December 5, 2002. The Ray et al. application is a continuation of application No. 09/286,047, filed on April 5, 1999, according to the bibliographic information on the face of the published Ray et al. application.

The respective Declarations of Vladimir A. Stoy and Gerald Gontarz under 37 CFR §1.131 aver that the inventors conceived of, and reduced to practice, the subject matter of the claims of the present application in the United States prior to April 5, 1999, i.e., before the earliest filing date attributable to Ray et al. Attached to the Declarations are certain papers from the laboratory notebook of Gerald Gontarz which describe a spinal nucleus implant that has shape memory from an Aquacryl polymer, i.e., a swellable, biomimetic plastic, having a hydrophobic phase having high crystallinity and low water content and with hydrophilic phase having low crystallinity and high water content, the biomimetic plastic having an inherent shape in which it has a relaxed polymer network in a state of full hydration, having an insertion shape in which it is at least partially dehydrated to a xerogel state and formable into a compacted mode for maximum efficiency of surgical insertion, and capable of anisotropic expansion due to partial rehydration in situ into an indwelling shape that substantially conforms to the size and shape of said cavity and is capable of osmotic movement of liquid therethrough in response to external pressure change to thereby increase and decrease liquid content in its hydrated state, the anisotropically swellable biomimetic plastic having preferred swelling in a vertical plane and suppressed minimal swelling or swelling in horizontal planes.

The laboratory notebook pages attached to the Declarations show the results of spinal nucleus implant swelling measurements in salt solutions on the page designated "A". A spinal nucleus implant made of "aquacryl" that has "shape memory" was made from spirals heated to 100°C in order to instill a shape, washed, plasticized and saved as samples 'G-9-107-A, is explicitly described on the page labeled "B". As can be seen from the present specification, e.g., Example 1 describes a spinal nucleus implant also made from Aquacryl (representative of an anisotropically swellable biomimetic plastic having the claimed properties). The Declarations further aver that the spinal nucleus implant described in the notebook pages had preferred swelling in a vertical plane and suppressed minimal swelling or swelling in horizontal planes.

Accordingly, the inventors have effectively sworn behind Ray et al. and the rejection under 35 USC §102(e) should be withdrawn.

Notwithstanding the inventors' earlier conception and reduction to practice regarding the filing date of Ray et al., it is noted for the record that applicants disagree with the rejection of claims 1-51 under 35 USC §102(e) for at least the reasons provided below.

Despite the contention in the Office Action that, "Ray et al. clearly disclose all the structural limitations claimed by all the 51 claims", there is absolutely no citation in the Office Action to any specific passage in Ray et al. In other words, the rejection is conclusory in nature and completely unsupported. It is respectfully submitted that nowhere in Ray et al. is there a teaching or suggestion, *inter alia*, of a swellable biomimetic plastic which is capable of anisotropic expansion due to partial rehydration in situ into an indwelling shape that substantially conforms to the size and shape of said cavity and is capable of osmotic movement of liquid therethrough in response to external pressure change to thereby increase and decrease liquid content in its hydrated state, the anisotropically swellable biomimetic plastic having preferred swelling in a vertical plane and suppressed minimal swelling or swelling in horizontal planes.

Ray et al. is directed to a prosthetic spinal disc nucleus having a formed hydrogel core which is surrounded by a constraining jacket. See ¶0017. It is the constraining jacket that limits expansion of the hydrogel core. See, e.g., ¶0022, last sentence. See, also, e.g., ¶0052. Accordingly, the constraining jacket conforms the hydrogel core to the dimensions of the constraining jacket upon hydration of the core. Ray et al. does not disclose an anisotropically swellable biomimetic plastic having preferred swelling in a vertical plane and suppressed minimal swelling or swelling in horizontal planes, since it is the constraining jacket and not the hydrogel core that defines the shape of the hydrated implant.

Applicants therefore do not concede that Ray et al. or US Patent No. 5,824,093 render the present claims 1-51 unpatentable under 35 USC §§102(e) or 103(a) even if the accompanying §131 Declarations “swearing behind” Ray et al. were not submitted herewith.

A good faith effort has been made to place the present application in condition for allowance. If there is any point requiring discussion prior to allowance, the Examiner is earnestly solicited to telephone the undersigned attorney for Applicants at the address below.

Respectfully submitted,



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